Complete Summary

GUIDELINE TITLE

Breast masses.

BIBLIOGRAPHIC SOURCE(S)

Breast masses. Philadelphia (PA): Intracorp; 2005. Various p. [21 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from April 1, 2005 to April 1, 2007.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Breast masses

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of breast masses that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Women with breast masses

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests:
    - Mammography
    - Clinical and self-breast examination
    - Ultrasound
    - Biopsy (fine needle aspiration, incisional, excisional)
    - Multiple tissue samplings
    - Radionuclide bone scan if indicated

Management/Treatment

1. No treatment for asymptomatic conditions
2. Oral danazol (Danocrine®, Cyclomen®) for pain relief
3. Physical therapy if indicated
4. Referral to specialists
5. Case management strategies, including case initiation, case management focus, and discharge

MAJOR OUTCOMES CONSIDERED

Sensitivity, utility, and accuracy of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or

the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed a published cost analysis.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Breasts pain, tenderness
- Discovery of "lump"
    - On breast self-exam (BSE)
    - Opportunistically
- Skin dimpling, thickening
- Nipple discharge reported

Objective Findings

- Asymmetry of breasts
- Breast tissue tender/painful to palpation

- On clinical breast exam:
    - Thickening of circumscribed area; may be movable and rubbery in texture
    - Margins may be indistinct or definitive
    - Variable size: lesions, usually not palpable <1 cm^3
- Unilateral flattening, dimpling, scaling, or irritation of breast skin
- Deviation of the nipple (including inversion) or breast contours
- Breast discharge can be expressed

Diagnostic Tests

- Mammography (breast radiography), standard first line study
    - Screening mammography combined with clinical breast exam (CBE) and BSE is highly effective in detecting breast nodules.
    - CBE should be performed close in time to mammography.
    - Implantation displacement views indicated for women after breast augmentation.
    - See Intracorp Imaging: Breast guideline for mammography approval criteria.
- Ultrasound (US), sonogram (see the Intracorp guideline Imaging: Breast)
    - Sonograms are useful in differentiating cystic lesions from solid masses.
    - US may resolve equivocal mammography findings, especially in dense breasts.
- Fine needle aspiration (FNA)/fine needle biopsy (FNB) (see the Intracorp guideline Breast Biopsy)
    - FNA both identifies cysts (diagnostic) and provides treatment (therapeutic).
    - Excisional biopsy - diagnostic gold standard
    - Needle core biopsy with computed axial tomography (CAT) scan, to aspirate palpable mass
    - Stereotactic needle core biopsy with CAT scan, to aspirate nonpalpable mass
    - Multiple tissue samplings are frequently taken.
    - The American Cancer Society recommends all suspicious lesions undergo aspiration/biopsy to rule out neoplasm/obtain a definitive diagnosis.
- Radionuclide bone scan
    - Bone scan with injectable dyes is indicated only when bone pain and documented breast cancer is confirmed.

Differential Diagnosis

- Breast cancer - histologic variants include:
    - Various forms of adenocarcinoma of the mammary ducts
    - Paget's disease of the nipple
    - Sarcoma of the breast
- Breast cysts - often painful and require aspiration
- Fibroadenomas - often asymptomatic
- Ductal papilloma - often leads to bloody secretion from nipple
- Sclerosing adenosis
- Fibrocystic disease

- Nodular hyperplasia
- Fat necrosis
- Thrombophlebitis of the breast

Treatment Options

- Asymptomatic situations often require no further treatment.
- For patients with breast pain and swelling (mastalgia), treatment to provide relief of symptoms may consist of oral androgen analog danazol (Danocrine® in U.S., Cyclomen® in Canada) (not to exceed 6 months).
    - NOTE: Danazol should be used only after the possibility of a malignancy has been excluded.
    - Care setting is unrestricted.

Duration of Medical Treatment

- Medical - Optimal: 2 day(s), Maximal: 5 day(s)
    - Depending on presence or recurrence of symptoms.

Additional information regarding primary care visit schedules, referral options, specialty care, physical therapy, and durable medical equipment is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- After biopsy for benign disease
- After biopsy for malignant disease

Case Management Directives (refer to the original guideline for detailed recommendations)

Case Initiation

Establish Case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- The American Joint Committee on Cancer encourages use of the "TNM" classification system (T=primary tumor size; N=lymph node involvement; M=metastasis).
- Provide contact information for local and national support groups.

Coordinate Care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity Deficit

- Patients with symptomatic disease may be unable to perform strenuous labor until medical treatment is begun.
- Workplace accommodation, such as deskwork restriction, with re-evaluation to assess treatment effectiveness and functional capacity, may be needed. (Patients with benign disease rarely require disability leave.)
- Document activity alteration as none, mild, moderate, severe, dependent, or bed-bound [based on most recent performance status] and interventions required.

Chemotherapy Intolerance

- Assess status, acute versus chronic, of toxic side effects on rapidly growing tissues, including bone marrow, epithelium, hair, sperm, and document intervention recommended.

Hemodynamic Instability

- Document bleeding complications, severity, and intervention recommended.

Immune Compromised

- Document establishment of protective isolation measures for a white blood cell count (WBC) less than 1,000/mm^3, implying dangerous susceptibly to infection.

Inadequate Nutrition

- Recommend to women who report painful breasts to refrain from caffeine consumption and to modify salt intake for 5 to 7 days prior to mammography.
- Use optimal goal of remaining within 10% of pretreatment weight to document hydration and nutrition deficit as mild, moderate, severe and response needed.

Mental and Emotional Alteration

- Ensure accurate diagnosis of any change in mental status.
- Document baseline or optimal mental and emotional functioning and their alterations due to cancer presence, comorbidity, surgery, or treatments.
- Assess and respond appropriately to the degree of debility caused by alterations listed in the original guideline document through benefit coordination or community resource activation.

Pain Control

- For discomfort caused by breast tissue inflammations, infection, or shooting pains, recommend adequate rest and hydration, careful personal hygiene, decreased salt and caffeine intake, local heat, and snug supportive bra.
- For persistent pain, assess the need for diuretics, analgesics, or oral contraceptives.
- Document optimal pain management by characterizing severity and interventions undertaken to remedy or manage pain.

Oncologic Emergencies

- Document presence of or developing oncologic emergencies and report to attending physician, surgeon, or activate emergency medical technician (EMT) system as necessary.

Radiation Intolerance

- Document presence and severity of radiation side effects.
- Initiate early interventions for complications of radiation therapy.

Respiratory Instability

- Document respiratory deficit as mild, moderate, severe, and dependent, and respiratory rehabilitation enhancement measures.

Skin Integrity Deficit

- Immediately refer conditions of non-lactation breast discharge, marked ulceration, unrelieved pain, or recurring fissures (longitudinal ulcerated areas) to the attending physician or specialist.
- Advise concerned patients that cyst size may fluctuate with menstrual cycle (larger, during premenstrual phase; smaller, postmenstrual).
- Instruct that fissures may develop while breast-feeding. Encourage daily warm water cleansing, non-friction drying, exposing to air, massaging lightly with lanolin, and using nipple shield during breast-feeding.
- Document severity of skin integrity disruption.

Terminal Care

- Document optimal comfort measures and palliative care initiatives.

Discharge

Discharge from Case Management (CM)

- Document return to independence or stabilized functional status and closing conversations with patient, caregiver, physician, pharmacist, and care providers.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefits

Appropriate diagnosis, treatment, and management of breast masses that assist medical management leaders in making appropriate benefit coverage determinations

Specific Potential Benefits

- Screening mammography combined with clinical breast exam (CBE) and breast self-exam (BSE) is highly effective in detecting breast nodules.
- Sonograms are useful in differentiating cystic lesions from solid masses.

POTENTIAL HARMS

Refer to the Case Management Focus section of the "Major Recommendations" field for information on potential complications and strategies to address them, or refer to the original guideline document.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Breast masses. Philadelphia (PA): Intracorp; 2005. Various p. [21 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2005)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Intracorp guidelines are available for a licensing fee via a password protected, secure Web site at www.intracorp.com.

Reprints of complete guideline content may be purchased for $35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 25, 2005. The information was verified by the guideline developer on June 7, 2005.

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DISCLAIMER

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